Guidance and Manufacturer's Declaration

Electromagnetic Emissions for QDR Horizon Systems

HOLOGIC®

A. A QDR Horizon system may need special precaution regarding EMC. It needs to be installed and put into service according to the EMC information provided in this manual. QDR Horizon can be affected by the operation of nearby portable and mobile RF communication equipment.

B. QDR Horizon systems shall be operated with the cables supplied with them and only those cables. Accessories supplied by Hologic shall be operated only in the manner described in their instructions. The use of accessories other than those supplied by Hologic may result in electromagnetic incompatibility and improper performance of the equipment.

Essential Performance: QDR Horizon maintains safe and effective performance (X-ray measurement of bone mineral content, BMC) when operated in the electromagnetic environment specified in tables below.

Warning: QDR Horizon should not be used adjacent to or stacked with other equipment.

NOTE The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.

IEC 60601-1-2 – Guidance and manufacturer's declaration – electromagnetic emissions – for all equipment and systems

Guidance and manufacturer's declaration - electromagnetic emissions		
QDR Horizon is intended for use in the electromagnetic environment specified below. The customer or the user of the QDR Horizon should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment — guidance**
RF emissions CISPR 11	Group 1	QDR Horizon uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	QDR Horizon is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

IEC 60601-1-2 – Guidance and manufacturer's declaration – electromagnetic immunity – for all equipment and systems

Guidance and manufacturer's declaration — electromagnetic immunity			
QDR Horizon is intended for use in the electromagnetic environment specified below. The customer or the user of QDR Horizon should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ± 15 kV air	±8 kV contact ± 15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 0,5 kV, ±1 kV differential mode ± 0,5 kV, ± 1 kV, ±2 kV common mode	± 0,5 kV, ±1 kV differential mode ± 0,5 kV, ± 1 kV, ±2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips IEC 61000-4-11	0 % *U*T; 0,5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % *U*T; 1 cycle and 70 % *U*T; 25/30 cycles Single phase: at 0°	0 % *U*T; 0,5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % *U*T; 1 cycle and 70 % *U*T; 25/30 cycles Single phase: at 0°	Mains power quality should be that of a typical commercial or hospital environment,
Voltage interruptions IEC 61000-4-11	0 % *U*T; 250/300 cycle	0 % *U*T; 250/300 cycle	Mains power quality should be that of a typical commercial or hospital environment
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE UT is the a.c. mains voltage prior to application of the test level.			

IEC 60601-1-2 – Guidance and manufacturer's declaration – electromagnetic immunity – for all equipment and systems that are not life-supporting

Guidance and manufacturer's declaration – electromagnetic immunity			
QDR Horizon is intended for use in the electromagnetic environment specified below. The customer or the user of the QDR Horizon should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment — guidance**
Conducted RF IEC 61000-4-6	3Vrms 150kHz to 80MHz	3Vrms 150kHz to 80MHz	Portable and mobile RF communications equipment should be used no closer to any part of QDR Series, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. $d = 1.2\sqrt{P}$
Radiated RF IEC 61000-4-3	3V/m 80MHz to 2.7GHz	3V/m 80MHz to 2.7GHz	**Recommended separation distance** $d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 80 MHz to 2,5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol: 

Proximity fields from RF wireless communications equipment IEC 61000-4-3	380 - 390 MHz 27 V/m; PM 50%; 18 Hz 430 - 470 MHz 28 V/m; (FM ±5 kHz, 1 kHz sine) PM; 18 Hz 704 - 787 MHz 9 V/m; PM 50%; 217 Hz 800 - 960 MHz 28 V/m; PM 50%; 18 Hz 1700 - 1990 MHz 28 V/m; PM 50%; 217 Hz 2400 - 2570 MHz 28 V/m; PM 50%; 217 Hz 5100 - 5800 MHz 9 V/m; PM 50%; 217 Hz	380 - 390 MHz 27 V/m; PM 50%; 18 Hz 430 - 470 MHz 28 V/m; (FM ±5 kHz, 1 kHz sine) PM; 18 Hz 704 - 787 MHz 9 V/m; PM 50%; 217 Hz 800 - 960 MHz 28 V/m; PM 50%; 18 Hz 1700 - 1990 MHz 28 V/m; PM 50%; 217 Hz 2400 - 2570 MHz 28 V/m; PM 50%; 217 Hz 5100 - 5800 MHz 9 V/m; PM 50%; 217 Hz	WARNING: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the device1), including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the QDR Horizon is used exceeds the applicable RF compliance level above, the QDR Horizon should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the QDR Horizon

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than [V_1] *V*/m.

IEC 60601-1-2 – Recommended separation distances between portable and mobile RF communications equipment and the equipment or systems - for equipment or systems that are not life-supporting

Recommended separation distances between portable and mobile RF communications equipment and the QDR Horizon

QDR Horizon is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of QDR Horizon can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and QDR Horizon as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m		
	150 kHz to 80 MHz $d = [\frac{3,5}{V_1}]\sqrt{P}$	80 MHz to 800 MHz $d = [\frac{3,5}{E_1}]\sqrt{P}$	800 MHz to 2,5 GHz $d = [\frac{7}{E_1}]\sqrt{P}$
0,01	0.12	0.12	0.23
0,1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.